PTO/SB/08A/B (09-06)

Approved for use through 03/31/2007. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Complete if Known Substitute for form 1449/PTO 10/644,267-Conf. #6263 **Application Number** INFORMATION DISCLOSURE Filing Date August 20, 2003-STATEMENT BY APPLICANT Heather L. Davis First Named Inventor 1632 Art Unit (Use as many sheets as necessary) A. M. Falk Examiner Name Sheet 3 of Attorney Docket Number O0277.70001US00

U.S. PATENT DOCUMENTS						
Exam <b>i</b> ner	Cita	CHA	Document Number	Publication Date	Name of Potentine or	Pages, Columns, Lines, Where
Initials*	No.1		MM-DD-YYYY		Relevant Passages or Relevant Figures Appear	
/AMF/	A23*	US-4,710,463	12-01-1987	Murray et al.		
	A24*	US-4,803,164	02-07-1989	Hitzeman et al.		
	A25*	US-4,839,277	06-13-1989	Sugahara et al.		
	A26*	US-4,957,869	09-18-1990	Arnot et al.		
	A27*		07-28-1998	Locht et al.	·	
	A28*	US-6,635,624	10-21-2003	Davis et al.		
Y	A29*	US-20020142978-A1	10-03-2002	Raz et al.		
/AMF/	A30*	US-20020192184-A1	12-19-2002	Carpentier		

FOREIGN PATENT DOCUMENTS								
Examiner	Cite	Foreign Patent Document	Publication	Name of Patentee or	Pages, Columns, Lines,			
Initials*	No.	Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>3</sup> (if known)	Date MM-DD-YYYY	Applicant of Cited Document	Where Relevant Passages or Relevant Figures Appear	T <sup>€</sup>		
/AMF/	В7	WO-9728259-A1	08-07-1997	The Regents of the University of California				
AMF/	B8	WO-2005004910-A2	01-20-2005	Intercell Ag		4		
/AMF/	B9	WO-2005039633-A1	05-06-2005	Mologen Ag	_			

"EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. "CITE NO.: Those application(s) which are marked with an single asterisk (\*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(iii)) because that application was filed after June 30, 2003 or is available in the IFW. Applicant's unique citation designation number (optional). See Kinds Codes of USPTO Patent Documents at <a href="https://www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. Applicant is to place a check mark here if English language Translation is attached.

	NON PATENT LITERATURE DOCUMENTS						
Examiner Cite No.¹  /AMF/ C56		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (blook, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²				
		ALPAR et al., Potential of particulate carriers for the mucosal delivery of DNA vaccines. Biochem Soc Trans. 1997 May;25(2):337S.					
	C57	BRANDA et al., Immune stimulation by an antisense oligomer complementary to the rev gene of HIV-1. Biochem Pharmacol. 1993 May 25;45(10):2037-43.					
	C58	CALAROTA et al., Cellular cytotoxic response induced by DNA vaccination in HIV-1-infected patients. Lancet. 1998 May 2;351(9112):1320-5.					
	C59	CHEN et al., Protective immunity induced by oral immunization with a rotavirus DNA vaccine encapsulated in microparticles. J Virol. 1998 Jul;72(7):5757-61.					
	C60	DAHESHIA et al., Immune induction and modulation by topical ocular administration of plasmid DNA encoding antigens and cytokines. Vaccine. 1998 Jul; 16(11-12):1103-10.					
V	C61	DAVIS et al., Plasmid DNA expression systems for the purpose of immunization. Curr Opin Biotechnol. 1997 Oct;8(5):635-46.					
/AMF/	C62	ETCHART et al., Class I-restricted CTL induction by mucosal immunization with naked DNA encoding measles virus haemagglutinin. J Gen Virol. 1997 Jul;78 ( Pt 7):1577-80.					

[Examiner	1A A 1 pm 11 1	Date	00/00/0007
	/Anne Marie Falk/	Date	09/29/2007
Signature	_ //\line wane i aliv	Considered	0312312001
			I

PTO/SB/08A/B (09-06)

Approved for use through 03/31/2007. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substi	tute for form 1449/P	סדי		Complete if Known		
				Application Number	10/644,267-Conf. #6263 August 20, 2003	
INF	FORMATI	ON DISC	CLOSURE	Filing Date		
STATEMENT BY APPLICANT				First Named Inventor	Heather L. Davis	
				Art Unit	1632	
	(Use as many she ets as necessary)			Examiner Name	A. M. Falk	
Sheet	2	of	3	Attorney Docket Number	O0277.70001US00	

<u>/AMF/</u>	C63	FIELDS et al., Fields' Virology. 2001;1:1153.	
	C64	GALLICHAN et al., Specific secretory immune responses in the female genital tract following intranasal immunization with a recombinant adenovirus expressing glycoprotein B of herpes simplex virus. Vaccine. 1995 Nov;13(16):1589-95.	
	C65	GEISSLER et al., Enhancement of cellular and humoral immune responses to hepatitis C virus core protein using DNA-based vaccines augmented with cytokine-expressing plasmids. J Immunol. 1997 Feb 1;158(3):1231-7.	
	C66	GRAMZINSKI et al., Immune response to a hepatitis B DNA vaccine in Aotus monkeys: a comparison of vaccine formulation, route, and method of administration. Mol Med. 1998 Feb;4(2):109-18.	
$\underline{\Psi}$	C67	HALPERIN et al., A phase I study of the safety and immunogenicity of recombinant hepatitis B surface antigen co-administered with an immunostimulatory phosphorothioate oligonucleotide adjuvant. Vaccine. 2003 Jun 2;21(19-20):2461-7.	
/AMF/	C68	HALPERIN et al., Comparison of the safety and immunogenicity of hepatitis B virus surface antigen co-administered with an immunostimulatory phosphorothioate oligonucleotide and a licensed hepatitis B vaccine in healthy young adults. Vaccine. 2006 Jan 9;24(1):20-6. Epub 2005 Sep 12. Abstract Only.	
	G <del>69</del>	HAYNES et al., Particle mediated nucleic acid immunization. J Biotechnol. 1996 Jan 26:44(1-3):37-42. Duplicate	
/AMF/	<u> </u>	HEDLEY et al., Microspheres containing plasmid-encoded antigens elicit cytotoxic T-cell responses. Nat Med. 1998 Mar;4(3):365-8.	
/AMF/	C71	JONES et al., Poly(DL-lactide-co-glycolide)-encapsulated plasmid DNA elicits systemic and mucosal antibody responses to encoded protein after oral administration. Vaccine. 1997 Jun; 15(8):814-7.	
/AMF/	C72	KLINMAN et al., Therapeutic applications of CpG-containing oligodeoxynucleotides. Antisense Nucleic Acid Drug Dev. 1998 Apr;8(2):181-4.	
	<del>673</del>	KUHOBER et al., DNA immunization induces antibody and cytotoxic T cell responses to hepatitis B core antigen in H-2b mice. J Immunol. 1996 May 15;156(10):3687-95. Duplic	ate
/AMF/	C74	LECLERC et al., The preferential induction of a Th1 immune response by DNA-based immunization is mediated by the immunostimulatory effect of plasmid DNA. Cell Immunol. 1997 Aug 1;179(2):97-106.	
	C75	LEE et al., Immuno-stimulatory effects of bacterial-derived plasmids depend on the nature of the antigen in intramuscular DNA inoculations. Immunology. 1998 Jul;94(3):285-9.	
	C76	MACGREGOR et al., First human trial of a DNA-based vaccine for treatment of human immunodeficiency virus type 1 infection: safety and host response. J Infect Dis. 1998 Jul;178(1):92-100.	
	C77 '	MCCLUSKIE et al., Novel strategies using DNA for the induction of mucosal immunity. Crit Rev Immunol. 1999; 19(4):303-29.	
	C78	MCCLUSKIE et al., Novel adjuvant systems. Curr Drug Targets Infect Disord. 2001 Nov;1(3):263-71.	
	C79	MCCLUSKIE et al., Mucosal immunization with DNA vaccines. Microbes Infect. 1999 Jul;1(9):685-98.	
	C80	MCCLUSKIE et al., The role of CpG in DNA vaccines. Springer Semin Immunopathol. 2000;22(1-2):125-32.	
V	C81	MCCLUSKIE et al., Route and method of delivery of DNA vaccine influence immune responses in mice and non-human primates. Mol Med. 1999 May;5(5):287-300.	
AMF/	C82	PAYETTE et al., History of vaccines and positioning of current trends. Curr Drug Targets Infect	

Examiner /Anne Marie Falk/	Date	09/29/2007
Signature // MITTE IVIATION AIN	Considered	09/29/2007

PTO/SB/08A/B (09-06)

Approved for use through 03/31/2007. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substit	ute for form 1449/P	то		Complete if Known		
				Application Number	10/644,267-Conf. #6263	
INF	ORMATI	ON DIS	CLOSURE	Filing Date	August 20, 2003	
ST	ATEMEN	T BY A	PPLICANT	First Named Inventor	Heather L. Davis	
	44.4			Art Unit	1632	
	(Use as many she ets as necessary)			Examiner Name	A. M. Falk	
heet	3	of	3	Attorney Docket Number	O0277.70001US00	

/AMF/	C83	ROMAN et al., Immunostimulatory DNA sequences function as T helper-1-promoting adjuvants. Nat Med. 1997 Aug;3(8):849-54.	
/AMF/	C84	RUBANYI, The future of human gene therapy. Mol Aspects Med. 2001 Jun;22(3):113-42.	
/AMF/	C85	TACKET et al., Phase 1 safety and immune response studies of a DNA vaccine encoding hepatitis 8 surface antigen delivered by a gene delivery device. Vaccine, 1999 Jul 16;17(22):2826-9.	
/AMF/	C86	UGEN et al., DNA vaccination with HIV-1 expressing constructs elicits immune responses in humans. Vaccine. 1998 Nov;16(19):1818-21.	
/AMF/	C87	WANG et al., Induction of antigen-specific cytotoxic T lymphocytes in humans by a malaria DNA vaccine. Science. 1998 Oct 16;282(5388):476-80.	
/AMF/	C88	WEERATNA et al., Reduction of antigen expression from DNA vaccines by coadministered oligodeoxynucleotides. Antisense Nucleic Acid Drug Dev. 1998 Aug;8(4):351-6.	
/AMF/	C89	WEERATNA et al., CpG DNA induces stronger immune responses with less toxicity than other adjuvants. Vaccine. 2000 Mar 6;18(17):1755-62.	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Examiner	/Anne Marie Falk/	Date	
	/Anne Marie Falk/	Cate	
Signature	mano rano	Considered	09/29/2007 <b> </b>
Olgriditate		Considered	

<sup>&</sup>lt;sup>3</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.